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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,777	10/09/2001	Max Schaldach	7040-45	6887

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

**Office Action Summary**

Application No.

09/974,777

Applicant(s)

SCHALDACH ET AL.

Examiner

Sarah K Webb

Art Unit

3731

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed 10/09/01 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered, unless accompanied by the corresponding US Patent.

### *Claim Objections*

2. Claims 1 and 66 are objected to because of the following informalities: the phrase "adjoin a turning point" in line 10 would make more sense if it read "adjoin at a turning point". Also, the phrase "the first *condition* of the stent" would read more clearly if changed to "first direction", since "the first direction" is also mentioned in line 13. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "in particular" in line 1. Claims 1 and 66 contain the phrase "extend curvedly in a first direction in the longitudinal direction". This phrase is indefinite, because it is unclear whether the first direction is the same or different from the longitudinal direction. These phrases render the claims indefinite, because it is unclear what is to

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be included in the claim. Claims 5-7 include the term "and/or", which is indefinite, because it is unclear what is to be included in the claim. Claim 31 includes the limitation "twice the period" in line 4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 11-30, 47, 48, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,193,747 to von Oepen.

The particular embodiment used for this rejection is shown in Figure 5 of von Oepen. The claim language was both broad and vague, but was given the most reasonable interpretation, which includes the structure of Figure 5. An attachment was provided to clarify the structural components of the von Oepen stent that correspond with limitations of the claims. Clearly, the stent is illustrated as having a number of annular portions connected by bars. The annular portions have a meandering, or curving, configuration. Bar elements connected at turning points make up the annular portions, and the bar elements have a "V-shape". The "V-shaped" bars curve in a "first direction" that is not longitudinal. The curves are continuous and uniform.

Regarding claims 5-7, von Oepen explains that the links, or connecting bars, form elastic elements, which means that they do not plastically deform (abstract, line 5). Since the connecting bars are elastic, they compensate for shortening of the stent during expansion by lengthening. Von Oepen describes the connecting bars as “spring elements” (column 14, line 4), which inherently means that they lengthen and shorten to compensate for length changes of the annular portions. This compensation could be described as “*substantial*”.

Regarding claims 11-16, the direction of curvature of the bar elements changes from one annular support to the next adjacent annular support.

Regarding claim 47, von Oepen explains that the connecting bars (spring elements) are adapted to increase the flexibility of the stent (column 4, lines 30-32).

Regarding claim 48, the connecting bars are clearly V-shaped.

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,776,161 to Globerman.

Globerman discloses a stent in Figure 16 that includes all the limitations of claims 1-10. Annular support portions have a meandering, or curving, configuration with bar elements connected at turning points. All the bar elements are curved in a direction that is non-longitudinal and the direction of this curve is the same for adjacent annular supports. The curves are uniform and continuous. Globerman explains that this configuration results in less strain at the connection points and that the stent is very flexible along the longitudinal axis (column 5, lines 35-55).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31-46, and 49-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen in view of US 6,261,319 to Kveen et al.

Von Oepen forms the connecting bars as rectilinear members, as they comprise straight segments. The connecting bars extend between two mutually facing turning points of two adjoining annular support portions. Von Oepen fails to connect two turning points that are displaced by one or two periods of the meandering pattern. Kveen discloses a stent with a very similar pattern to that of von Oepen, in that the pattern includes sinusoidal annular rings connected by V-shaped bars (Figure 4A). Kveen teaches that the connecting bars can engage a central region of the bar elements, and that the connecting bars can connect turning points that are offset by a period of the sinusoidal pattern. Kveen further teaches that this type of connecting bar, or link, is just a substitute for other link configurations, and that the links provide flexibility for the stent (column 13, lines 6-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to connect displaced turning points at a central region of the bar elements, as taught by Kveen, with the V-shaped bars of von Oepen, as this is just an alternate type of flexible link that connects turning points of sinusoidal annular rings.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Figure 5 of US 6,416,539 to Hassdenteufel illustrates a stent with V-shaped links connecting displaced peaks of adjacent rings. US 6,325,821 to Gashino et al. discloses a stent in Figure 1 that has V-shaped links connected to the central regions of adjacent bar elements. US 5,843,175 and US 6,402,606 to Frantzen disclose stents with sinusoidal annular rings connected by V-shaped links.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb  
Examiner  
Art Unit 3731

sw  
February 5, 2003

  
Michael Milano  
Supervisory Patent Examiner  
Art Unit 3700

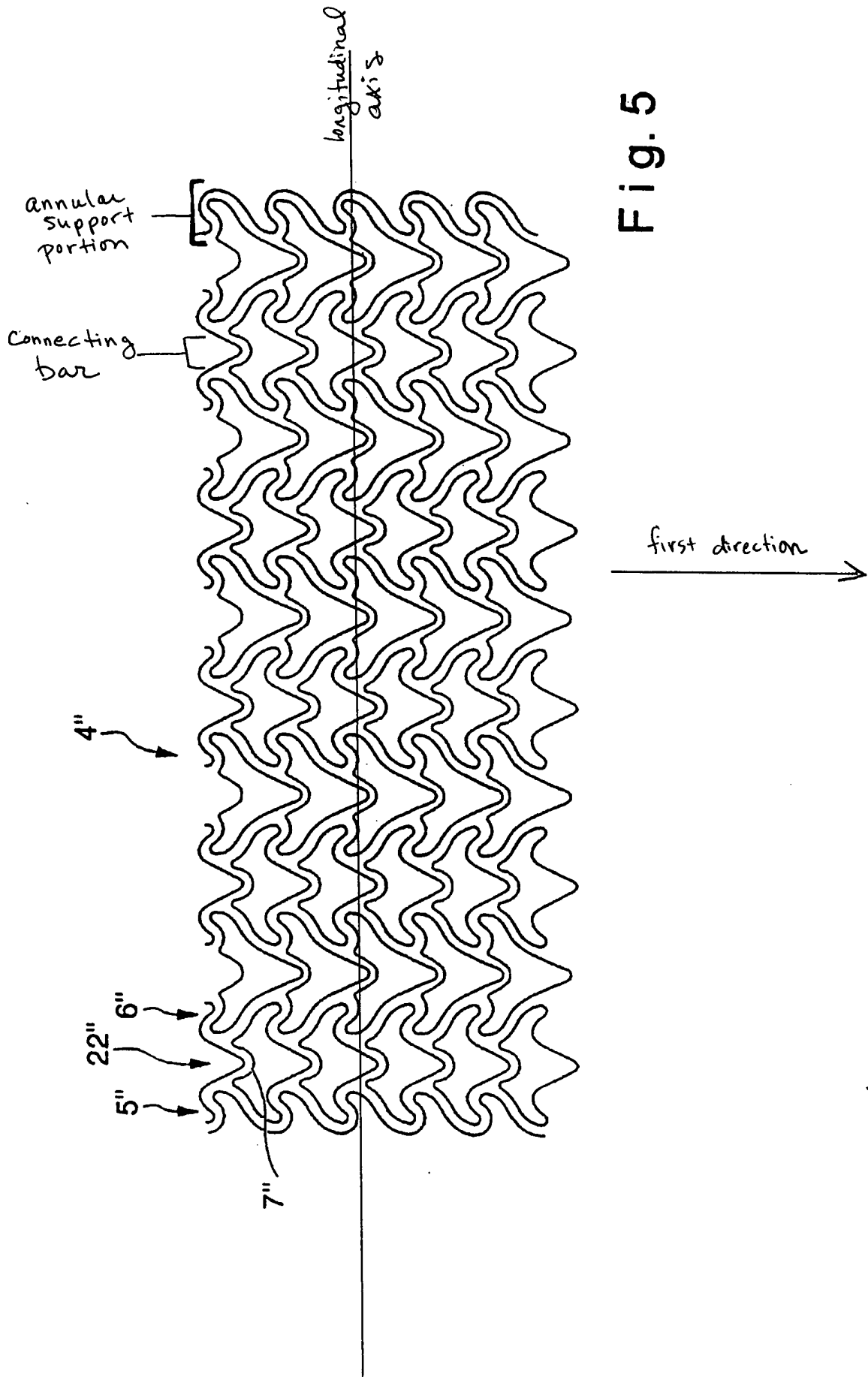


Fig. 5